Remarks

Claims 1, 11, 12, 14-23, 29, 37-40, 50-53, 59, 60, 84, 87-159 are presently pending in the subject application.

Reconsideration and allowance are respectfully requested in view of the above amendments and the following remarks.

Claims 6-10 and 13 are canceled herein without prejudice to the prosecution of the subject matter of this claims in this or a future continuing application.

The claims have been amended herein to, *inter alia*, introduce length limitations to the target binding portions of the recited hybridization assay probes, amplification oligonucleotides and helper oligonucleotides. *See, e.g.*, specification at page 4, lines 22-26; page 5, lines 10-12; and page 31, lines 7-9. The claims have further been amended herein to specify the claimed probes and amplification oligonucleotides do not include base regions in addition to the recited target binding regions that are capable of stably binding to the target nucleic acid under the indicated conditions of use. *See, e.g.*, specification at page 20, lines 22-25; and page 44, lines 7-11. The claims have also been amended herein to replace the phrase "amplification primer" with the phrase "amplification oligonucleotide" to clarify that the claimed amplification oligonucleotides do not have function as primers. *See, e.g.*, specification at page 20, lines 19-22. Additionally, to clarify that the claimed probes will bind to and form a hybrid stable for detection with nucleic acid from more than one species of *Cryptosporidium*, the claims have been amended herein to replace the phrase "a *Cryptosporidium* organism" with "*Cryptosporidium* organisms." *See, e.g.*, specification at page 43, lines 3-8. Finally, many of the claims have been amended herein to simplify and/or clarify the claim language consistent with Applicants' disclosure. A clean copy of the amended claims is attached hereto for the Examiner's convenience. *See* Attachment A.

Non-Elected Subject Matter

Claims 87-92, 100-105, 108-113, 127-132 and 145-150 have been withdrawn by the Examiner as being drawn to non-elected subject matter. Applicants respectfully request reconsideration by the Examiner, as the sequences recited in the withdrawn claims are contained within the language of the claims from which they depend (*i.e.*, claims in which the target sequence is one of sequence identifiers 6, 10, 14 and 18). As such, Applicants submit that maintenance of the withdrawn claims does not increase the Examiner's search burden, as a search of the broader claims *de facto* includes a search of the more restrictive language of the withdrawn claims.

Objection to the Specification

The disclosure is objected to by the Examiner for containing an embedded hyperlink. Applicants provided this hyperlink to ensure that their disclosure fully enabled the claimed invention and did not intend for this hyperlink to be an active link. Accordingly, withdrawal of this objection is respectfully requested with the understanding that the Office will disable this hyperlink when preparing the text to be loaded onto the USPTO web database. *See* MPEP § 608.01.

Rejection Under 35 U.S.C. § 112

Claims 1, 6-23, 29, 37-40, 50-53, 59, 60, 84, 93-99, 106, 107, 114-126, 133-144 and 151-159 stand rejected by the Examiner under 35 U.S.C. § 112, first paragraph, as lacking written description support. Applicants submit that this rejection is rendered moot by the amendments to the claims herein. Accordingly, withdrawal of this rejection is respectfully requested.

Rejections Under 35 U.S.C. § 102

Claims 1, 6, 7, 19, 20-22 and 93 stand rejected by the Examiner under 35 U.S.C. § 102(a) as being anticipated by Nelson (GenBank Accession No. AA167899, August 23, 2000). The Examiner contends that Nelson discloses a nucleic acid from the *Cryptosporidium parvum* 18S

ribosomal RNA gene which contains the sequence of SEQ ID NO:6. While the Examiner has not addressed all of the limitations of the rejected claims, Applicants nevertheless submit that basis for this rejection is rendered moot by the amendments to the claims herein. Accordingly, withdrawal of this rejection is respectfully requested.

Claims 1, 6, 7, 19, 20-22 and 93 stand rejected by the Examiner under 35 U.S.C. § 102(e) as being anticipated by Wick *et al.* (U.S. Patent No. 6,063,604, May 16, 2000). In support of this rejection, the Examiner contends that Wick discloses a nucleic acid from the *Cryptosporidium parvum* 18S ribosomal RNA gene which contains the sequence of SEQ ID NO:6. While the Examiner has not addressed all of the limitations of the rejected claims, Applicants nevertheless submit that the basis for this rejection is rendered moot by the amendments to the claims herein. Accordingly, withdrawal of this rejection is respectfully requested.

Claims 1, 6, 7, 19-23, 23, 93-99, 106 and 107 stand rejected by the Examiner under 35 U.S.C. § 102(b) as being anticipated by Brennan (U.S. Patent No. 5,474,796, December 12, 1995). In setting forth this rejection, the Examiner submits that the claims are directed to a probe comprising an at least 10 contiguous base region which is at least 80% complementary to SEQ ID NO:1. Applicants note, however, that SEQ ID NO:1 is not recited in any of the presently pending claims. The Examiner also contends that Brennan discloses oligonucleotides having 10 nucleotides each and that the oligoonucleotides of Brennan represent every possible permutation of the instant claims. In response, Applicants first note that the Examiner has not identified where Brennan provides support for this conclusion. Second, the Examiner has not established how Brennan enables the specifically claimed hybridization assay probes and probe mixes. Notwithstanding, Applicants submit that the basis for this rejection is rendered moot by the amendments to the claims herein. Accordingly, withdrawal of this rejection is respectfully requested.

Rejections Under 35 U.S.C. § 103

Claims 1, 6-10, 14, 19-23, 29, 37-40, 50-53, 59, 60, 84, 93-99, 106, 107, 114-126, 133-144 and 150-159 stand rejected by the Examiner under 35 U.S.C. § 103(a) as being unpatentable over Zhu *et al.* (*J. Infectious Disease*, Vol. 177, pages 1443-1446, 1998) in view of Williams *et al.* (U.S. Patent No. 6,146,855, November 14, 2000) and Xiao *et al.* (*Applied and Environmental Microbiology*, Vol. 65, pages 3386-3391, August 1999) in view of Hogan *et al.* (U.S. Patent No. 5,595,874, 1997). Applicants respectfully traverse this rejection for the reasons that follow.

Zhu is cited by the Examiner for teaching a method of detecting *Cryptosporidium* using genus-specific primers from the 18S rRNA. Although Zhu does not teach using SEQ ID NO:6 as the target sequence for the probes and primers, the Examiner urges that Williams provides an alignment for the relatedness of *C. parvum*, *C. muris* and *C. baileyi*. Xiao is cited by the Examiner for teaching a comparison of various isolates of seven *Cryptosporidium* species, including isolates from the species *C. parvum*, *C. wrairi*, *C. muris* and *C. baileyi*. Xiao is also cited for teaching that nucleotide sequences of these isolates were deposited with GenBank under various accession numbers and that sequences of these isolates were aligned and differences among the isolates were identified. Finally, Hogan is cited by the Examiner for teaching a method of comparing rRNA variable region sequences to distinguish between organisms. From these disclosures, the Examiner concludes that it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to modify the genus-specific primers of Zhu using the alignments provided by Williams and Xiao and the guidance taught by Hogan to obtain the invention as a whole.

Zhu teaches two sets of PCR primer pairs for amplifying a region of the small subunit rRNA gene of *Cryptosporidium parvum*. *See* Zhu at paragraph bridging cols. 1 and 2 on page 1444. One set of Zhu's primer pairs is specific for the genus *Cryptosporidium*, while the other set is specific for *Cryptosporidium parvum*. The sequence of the probe Zhu used to detect amplification

product is not disclosed. However, a comparison of the primer sequences disclosed by Zhu with the *C. parvum* sequence disclosed in FIG. 3 of Williams reveals that the primers of Zhu are not amplifying the region targeted by Applicants' claimed probes. Williams, in turn, teaches four preferred detection oligonucleotides, each of which targets a region contained within at least one of the two regions amplified by Zhu's primer sets. *See* Williams at col. 2, lines 10-23, and FIG. 3. Thus, if anything, Zhu and Williams read together would have motivated those skilled in the art at the time the claimed invention was made to try to find additional probe targets within the regions amplified by the primers of Zhu. Xiao would not have altered this motivation, as Xiao merely discloses that the small subunit rRNA gene sequences of other *Cryptosporidium* species had been deposited with GenBank, and that he used non-specific restriction products in a PCR-restriction fragment length polymorphism test to differentiate most *Cryptosporidium* species and *C. parvum* genotypes (sequence analysis of PCR products was needed to differentiate *C. wrairi* from some *C. parvum* genotypes). *See* Xiao at abstract and pages 3388-3389. And Hogan, while teaching a method for the identification of variable regions used to distinguish between organisms, does not provide a specific disclosure of regions useful for targeting *C. parvum* ribosomal nucleic acid or, therefore, the likelihood of success in identifying other regions in addition to those disclosed by Zhu and Williams. Hence, Applicants submit that the claimed invention is fully patentable in view of the art of record and, accordingly, withdrawal of this rejection is respectfully requested.

Claims 11-13 and 15-18 stand rejected by the Examiner under 35 U.S.C. § 103(a) as being unpatentable over Zhu *et al.* (*J. Infectious Disease*, Vol. 177, pages 1443-1446, 1998) in view of Williams *et al.* (U.S. Patent No. 6,146,855, November 14, 2000) and Xiao *et al.* (*Applied and Environmental Microbiology*, Vol. 65, pages 3386-3391, August 1999) in view of Hogan *et al.* (U.S. Patent No. 5,595,874, 1997), as applied to claims 1, 6-10, 14, 19-23, 29, 37-40, 50-53, 59, 60, 84, 93-99, 106-107, 114-126, 133-144 and 150-159, and further in view of Becker *et al.* (U.S. Patent No. 6,361,945, March 26, 2002). Applicants submit that the teachings of Becker do not overcome the

deficiencies noted above in the teachings of Zhu and Williams when combined with the teachings of Xiao and Hogan. Accordingly, withdrawal of this rejection is respectfully requested.

Applicants submit that the subject application is in condition for allowance and early Notice to that effect is earnestly solicited.

Please charge any fees due in connection with this Reply, including the fee for a three-month extension of time, to Deposit Account No. 07-0835 in the name of Gen-Probe Incorporated.

Certificate of Transmission

I hereby certify that this correspondence (and any referred to as attached) is being sent by facsimile to 703-872-9306 on the date indicated below to the Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Respectfully Submitted,

Date: December 23, 2003 By: _____

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ATTACHMENT A

Clean Copy of Amended Claims

1. (Currently Amended) A hybridization assay probe comprising a target binding region from 18 to 35 bases in length that hybridizes to a target sequence present in target nucleic acid derived from a *Cryptosporidium parvum* organism in a test sample under stringent conditions to form a probe:target hybrid stable for detection, said target sequence being selected from the group consisting of SEQ ID NO:6, SEQ ID NO:10, SEQ ID NO:14 and SEQ ID NO:18, wherein said probe does not comprise a base region in addition to said target binding region that is capable of stably binding to said target nucleic acid under said conditions, and wherein said probe does not hybridize to nucleic acid derived from a *Cryptosporidium muris*, *Cryptosporidium baileyi* or *Cryptosporidium wrairi* organism to form a probe:non-target hybrid stable for detection under said conditions.

Claims 2-10 (Canceled)

11. (Currently Amended) The probe of claim 1, wherein said probe contains at least two base regions that hybridize to each other when said probe is not hybridized to said target sequence under said conditions.

12. (Currently Amended) The probe of claim 1, wherein said probe comprises at least one base region that does not stably hybridize to nucleic acid derived from a *Cryptosporidium parvum* organism under said conditions.

13. Canceled

14. (Original) The probe of claim 1 further comprising a detectable label.

15. (Currently Amended) The probe of claim 11 further comprising a group of interacting labels.

16. (Original) The probe of claim 15, wherein said interacting labels include a luminescent label and a quencher label.

17. (Currently Amended) The probe of claim 1, wherein said target binding region includes at least one ribonucleotide modified to include a 2'-O-methyl substitution to the ribofuranosyl moiety.

18. (Currently Amended) The probe of claim 1, wherein a pseudo peptide backbone joins at least a portion of the bases of said target binding region.

19. (Currently Amended) The probe of claim 1, wherein said conditions comprise 100 mM succinic acid, 2% (w/v) LLS, 15 mM aldrithiol-2, 1.2 M LiCl, 20 mM EDTA, 3% (v/v) ethyl alcohol (absolute), pH 4.7, and a test sample temperature of about 60°C.

20. (Currently Amended) The probe of claim 1, wherein the base sequence of said target binding region is at least 80% complementary to the base sequence of said target sequence.

21. (Currently Amended) The probe of claim 1, wherein the base sequence of said probe is at least 80% complementary to the base sequence of said target sequence.

22. (Currently Amended) The probe of claim 1, wherein the base sequence of said probe is fully complementary to the base sequence of said target sequence.

23. (Currently Amended) A probe mix comprising said probe of claim 1 and a first helper oligonucleotide from 18 to 35 bases in length that hybridizes to a target sequence selected from the group consisting of SEQ ID NO:29, SEQ ID NO:33, SEQ ID NO:37 and SEQ ID NO:41 under stringent conditions.

Claims 24-28 (Canceled)

29. (Currently Amended) The probe mix of claim 23 further comprising a second helper oligonucleotide from 18 to 35 bases in length that hybridizes to a target sequence selected from the group consisting of SEQ ID NO:32, SEQ ID NO:36, SEQ ID NO:40 and SEQ ID NO:44 under stringent conditions.

Claims 30-36 (Canceled)

37. (Currently Amended) A method for determining the presence of a *Cryptosporidium parvum* organism in a test sample, said method comprising the steps of:

contacting said test sample with said probe of claim 1 under stringent conditions; and

determining whether a probe:target hybrid has formed as an indication of the presence of a *Cryptosporidium parvum* organism in said test sample.

38. (Currently Amended) The method of claim 37 further comprising providing to said test sample a first amplification oligonucleotide under amplification conditions, said first amplification oligonucleotide comprising a target binding region from 18 to 40 bases in length that hybridizes to a target sequence selected from the group consisting of SEQ ID NO:48, SEQ ID NO:54, SEQ ID NO:60 and SEQ ID NO:66 under said amplification conditions, wherein said first amplification oligonucleotide does not comprise a base region in addition to said target binding region that is capable of stably binding to a target nucleic acid containing said target sequence under said amplification conditions, and wherein said first amplification oligonucleotide optionally includes a 5' sequence that is recognized by an RNA polymerase or that enhances initiation or elongation by an RNA polymerase.

39. (Currently Amended) The method of claim 38 further comprising providing to said test sample a second amplification oligonucleotide under said amplification conditions, said second amplification oligonucleotide comprising a target binding region from 18 to 40 bases in length that hybridizes to a target sequence selected from the group consisting of SEQ ID NO:45, SEQ ID NO:51, SEQ ID NO:57 and SEQ ID NO:63 under said amplification conditions, wherein

said second amplification oligonucleotide does not comprise a base region in addition to said target binding region that is capable of stably binding to a target nucleic acid containing said target sequence under said amplification conditions, and wherein said second amplification oligonucleotide optionally includes a 5' sequence that is recognized by an RNA polymerase or that enhances initiation or elongation by an RNA polymerase.

40. (Currently Amended) The method of claim 38 further comprising providing to said test sample a second amplification oligonucleotide under amplification conditions, said second amplification oligonucleotide comprising a target binding region from 18 to 40 bases in length that hybridizes to a target sequence selected from the group consisting of SEQ ID NO:46, SEQ ID NO:52, SEQ ID NO:58 and SEQ ID NO:64 under said amplification conditions, wherein said second amplification oligonucleotide does not comprise a base region in addition to said target binding region that is capable of stably binding to a target nucleic acid containing said target sequence under said amplification conditions, and wherein said second amplification oligonucleotide optionally includes a 5' sequence that is recognized by an RNA polymerase or that enhances initiation or elongation by an RNA polymerase.

Claims 41-49 (Canceled)

50. (Currently Amended) A method for determining the presence of a *Cryptosporidium parvum* organism in a test sample, said method comprising the steps of:

contacting said test sample with said probe of claim 20 under stringent conditions; and

determining whether a probe:target hybrid has formed as an indication of the presence of a *Cryptosporidium parvum* organism in said test sample.

51. (Currently Amended) A method for determining the presence of a *Cryptosporidium parvum* organism in a test sample, said method comprising the steps of:

contacting said test sample with said probe of claim 21 under stringent conditions; and

determining whether a probe:target hybrid has formed as an indication of the presence of a *Cryptosporidium parvum* organism in said test sample.

52. (Currently Amended) A method for determining the presence of a *Cryptosporidium parvum* organism in a test sample, said method comprising the steps of:

contacting said test sample with said probe of claim 22 under stringent conditions; and

determining whether a probe:target hybrid has formed as an indication of the presence of a *Cryptosporidium parvum* organism in said test sample.

53. (Currently Amended) A kit comprising, in packaged combination, first and second oligonucleotides for use in determining the presence of a *Cryptosporidium parvum* organism in a test sample, each of said oligonucleotides a target sequence in target nucleic acid derived from a *Cryptosporidium parvum* organism under hybridization conditions, said target binding region of said first oligonucleotide being from 18 to 35 bases in length and said target binding region of said second oligonucleotide being from 18 to 40 bases in length,

wherein said target sequence of said first oligonucleotide is selected from the group consisting of SEQ ID NO:6, SEQ ID NO:10, SEQ ID NO:14 and SEQ ID NO:18,

wherein said target sequence of said second oligonucleotide is selected from the group consisting of SEQ ID NO:48, SEQ ID NO:54, SEQ ID NO:60 and SEQ ID NO:66,

wherein neither of said first and second oligonucleotides comprises a base region in addition to said target binding region that is capable of stably binding to said target nucleic acid under said conditions, and

wherein said second oligonucleotide optionally includes a 5' sequence that is recognized by an RNA polymerase or that enhances initiation or elongation by an RNA polymerase

Claims 54-58 (Canceled)

59. (Currently Amended) The kit of claim 53 further comprising a third oligonucleotide, said third oligonucleotide comprising a target binding region from 18 to 40 bases in length that hybridizes to a target sequence present in target nucleic acid derived from a *Cryptosporidium parvum* organism under hybridization conditions, said target sequence being selected from the group consisting of SEQ ID NO:45, SEQ ID NO:51, SEQ ID NO:57 and SEQ ID NO:63, wherein said third oligonucleotide does not comprise a base region in addition to said target binding region that is capable of stably binding to said target nucleic acid under said conditions, and wherein said third oligonucleotide optionally includes a 5' sequence that is recognized by an RNA polymerase or that enhances initiation or elongation by an RNA polymerase.

60. (Currently Amended) The kit of claim 53 further comprising a third oligonucleotide, said third oligonucleotide comprising a target binding region from 18 to 40 bases in length that hybridizes to a target sequence present in target nucleic acid derived from a *Cryptosporidium parvum* organism under hybridization conditions, said target sequence being selected from the group consisting of SEQ ID NO:46, SEQ ID NO:52, SEQ ID NO:58 and SEQ ID NO:64, wherein said third oligonucleotide does not comprise a base region in addition to said target binding region that is capable of stably binding to said target nucleic acid under said conditions, and wherein said third oligonucleotide optionally includes a 5' sequence that is recognized by an RNA polymerase or that enhances initiation or elongation by an RNA polymerase.

Claims 61-83 (Canceled)

84. (Currently Amended) A kit comprising, in packaged combination, first and second oligonucleotides for use in determining the presence of a *Cryptosporidium parvum* organism in a test sample, each of said oligonucleotides comprising a target binding region from 18 to 35 bases in length that hybridizes to a target sequence present in target nucleic acid derived from a *Cryptosporidium parvum* organism under stringent conditions, wherein said target sequence of said first oligonucleotide is selected from the group consisting of SEQ ID NO:6, SEQ ID NO:10, SEQ ID NO:14 and SEQ ID NO:18,

wherein said target sequence of said second oligonucleotide is selected from the group consisting of SEQ ID NO:29, SEQ ID NO:33, SEQ ID NO:37 and SEQ ID NO:41,

wherein neither of said first and second oligonucleotides comprises a base region in addition to said target binding region that is capable of stably binding to said target nucleic acid under said conditions, and

wherein said first oligonucleotide does not hybridize to nucleic acid derived from a *Cryptosporidium muris*, *Cryptosporidium baileyi* or *Cryptosporidium wrairi* organism to form a probe:non-target hybrid stable for detection under said conditions.

Claims 85-86 (Canceled)

87. (Withdrawn) The probe of claim 1, wherein the base sequence of said probe comprises the base sequence of SEQ ID NO:5, SEQ ID NO:9, SEQ ID NO:13 or SEQ ID NO:17.

88. (Withdrawn) The probe of claim 1, wherein the base sequence of said probe consists of or is contained within the base sequence of SEQ ID NO:5, SEQ ID NO:9, SEQ ID NO:13 or SEQ ID NO:17.

89. (Withdrawn) The probe of claim 1, wherein the base sequence of said probe consists of the base sequence of SEQ ID NO:5, SEQ ID NO:9, SEQ ID NO:13 or SEQ ID NO:17.

90. (Withdrawn) The probe of claim 1, wherein the base sequence of said probe comprises the base sequence of SEQ ID NO:7, SEQ ID NO:11, SEQ ID NO:15 or SEQ ID NO:19.

91. (Withdrawn) The probe of claim 1, wherein the base sequence of said probe consists of or is contained within the base sequence of SEQ ID NO:7, SEQ ID NO:11, SEQ ID NO:15 or SEQ ID NO:19.

92. (Withdrawn) The probe of claim 1, wherein the base sequence of said probe consists of the base sequence of SEQ ID NO:7, SEQ ID NO:11, SEQ ID NO:15 or SEQ ID NO:19.

93. (Currently Amended) The probe of claim 20, wherein the base sequence of said target binding region is fully complementary to the base sequence of said target sequence.

94. (Currently Amended) A probe mix comprising said probe of claim 20 and a first helper oligonucleotide up to 35 bases in length and having a base sequence that is at least 80% complementary to the base sequence of a target sequence selected from the group consisting of SEQ ID NO:29, SEQ ID NO:33, SEQ ID NO:37 and SEQ ID NO:41, wherein said first helper oligonucleotide hybridizes to said target sequence under stringent conditions.

95. (Currently Amended) The probe mix of claim 94 further comprising a second helper oligonucleotide up to 35 bases in length and having a base sequence that is at least 80% complementary to the base sequence of a target sequence selected from the group consisting of SEQ ID NO:32, SEQ ID NO:36, SEQ ID NO:40 and SEQ ID NO:44, wherein said second helper oligonucleotide hybridizes to said target sequence under stringent conditions.

96. (Currently Amended) A probe mix comprising said probe of claim 21 and a first helper oligonucleotide, wherein the base sequence of said first helper oligonucleotide is at least 80% complementary to the base sequence of a target sequence selected from the group consisting of SEQ ID NO:29, SEQ ID NO:33, SEQ ID NO:37 and SEQ ID NO:41, wherein said first helper oligonucleotide hybridizes to said target sequence under stringent conditions.

97. (Currently Amended) The probe mix of claim 96 further comprising a second helper oligonucleotide, wherein the base sequence of said second helper oligonucleotide is at least 80% complementary to the base sequence of a target sequence selected from the group consisting of SEQ ID NO:32, SEQ ID NO:36, SEQ ID NO:40 and SEQ ID NO:44, wherein said second helper oligonucleotide hybridizes to said target sequence under stringent conditions.

98. (Currently Amended) A probe mix comprising said probe of claim 22 and a first helper oligonucleotide, wherein the base sequence of said first helper oligonucleotide is fully complementary to the base sequence of a target sequence selected from the group consisting of SEQ ID NO:29, SEQ ID NO:33, SEQ ID NO:37 and SEQ ID NO:41.

99. (Currently Amended) The probe mix of claim 98 further comprising a second helper oligonucleotide, wherein the base sequence of said second helper oligonucleotide is fully complementary to the base sequence of a target sequence selected from the group consisting of SEQ ID NO:32, SEQ ID NO:36, SEQ ID NO:40 and SEQ ID NO:44.

100. (Withdrawn) The probe mix of claim 23, wherein the base sequence of said probe comprises the base sequence of SEQ ID NO:5, SEQ ID NO:9, SEQ ID NO:13 or SEQ ID NO:17.

101. (Withdrawn) The probe mix of claim 23, wherein the base sequence of said probe consists of or is contained within the base sequence of SEQ ID NO:5, SEQ ID NO:9, SEQ ID NO:13 or SEQ ID NO:17.

102. (Withdrawn) The probe mix of claim 23, wherein the base sequence of said probe consists of the base sequence of SEQ ID NO:5, SEQ ID NO:9, SEQ ID NO:13 or SEQ ID NO:17.

103. (Withdrawn) The probe mix of claim 23, wherein the base sequence of said probe comprises the base sequence of SEQ ID NO:7, SEQ ID NO:11, SEQ ID NO:15 or SEQ ID NO:19.

104. (Withdrawn) The probe mix of claim 23, wherein the base sequence of said probe consists of or is contained within the base sequence of SEQ ID NO:7, SEQ ID NO:11, SEQ ID NO:15 or SEQ ID NO:19.

105. (Withdrawn) The probe mix of claim 23, wherein the base sequence of said probe consists of the base sequence of SEQ ID NO:7, SEQ ID NO:11, SEQ ID NO:15 or SEQ ID NO:19.

106. (Currently Amended) A probe mix comprising the probe of claim 93 and a first helper oligonucleotide up to 35 bases in length and having a base sequence that is fully complementary to the base sequence of a target sequence selected from the group consisting of SEQ ID NO:29, SEQ ID NO:33, SEQ ID NO:37 and SEQ ID NO:41, wherein said first helper oligonucleotide hybridizes to said target sequence under stringent conditions.

107. (Currently Amended) The probe mix of claim 106 further comprising a second helper oligonucleotide up to 35 bases in length and having a base sequence that is fully complementary to the base sequence of a target sequence selected from the group consisting of SEQ ID NO:32, SEQ ID NO:36, SEQ ID NO:40 and SEQ ID NO:44, wherein said second helper oligonucleotide hybridizes to said target sequence under stringent conditions.

108. (Withdrawn) The method of claim 37, wherein the base sequence of said probe comprises the base sequence of SEQ ID NO:5, SEQ ID NO:9, SEQ ID NO:13 or SEQ ID NO:17.

109. (Withdrawn) The method of claim 37, wherein the base sequence of said probe consists of or is contained within the base sequence of SEQ ID NO:5, SEQ ID NO:9, SEQ ID NO:13 or SEQ ID NO:17.

110. (Withdrawn) The method of claim 37, wherein the base sequence of said probe consists of the base sequence of SEQ ID NO:5, SEQ ID NO:9, SEQ ID NO:13 or SEQ ID NO:17.

111. (Withdrawn) The method of claim 37, wherein the base sequence of said probe comprises the base sequence of SEQ ID NO:7, SEQ ID NO:11, SEQ ID NO:15 or SEQ ID NO:19.

112. (Withdrawn) The method of claim 37, wherein the base sequence of said probe consists of or is contained within the base sequence of SEQ ID NO:7, SEQ ID NO:11, SEQ ID NO:15 or SEQ ID NO:19.

113. (Withdrawn) The method of claim 37, wherein the base sequence of said probe consists of the base sequence of SEQ ID NO:7, SEQ ID NO:11, SEQ ID NO:15 or SEQ ID NO:19.

114. (Currently Amended) The method of claim 50 further comprising providing to said test sample a first amplification oligonucleotide under amplification conditions, said first amplification oligonucleotide comprising a target binding region from 18 to 40 bases in length that hybridizes to a target sequence selected from the group consisting of SEQ ID NO:48, SEQ ID NO:54, SEQ ID NO:60 and SEQ ID NO:66 under said amplification conditions, wherein said first amplification oligonucleotide does not comprise a base region in addition to said target binding region that is capable of stably binding to a target nucleic acid containing said target sequence under said amplification conditions, and wherein said first amplification oligonucleotide optionally includes a 5' sequence that is recognized by an RNA polymerase or that enhances initiation or elongation by an RNA polymerase.

115. (Currently Amended) The method of claim 114 further comprising providing to said test sample a second amplification oligonucleotide under said amplification conditions, said second amplification oligonucleotide comprising a target binding region from 18 to 40 bases in length that hybridizes to a target sequence selected from the group consisting of SEQ ID NO:45, SEQ ID NO:51, SEQ ID NO:57 and SEQ ID NO:63 under said amplification conditions, wherein said second amplification oligonucleotide does not comprise a base region in addition to said target

binding region that is capable of stably binding to a target nucleic acid containing said target sequence under said amplification conditions, and wherein said second amplification oligonucleotide optionally includes a 5' sequence that is recognized by an RNA polymerase or that enhances initiation or elongation by an RNA polymerase.

116. (Currently Amended) The method of claim 114 further comprising providing to said test sample a second amplification oligonucleotide under said amplification conditions, said second amplification oligonucleotide comprising a target binding region from 18 to 40 bases in length that hybridizes to a target sequence selected from the group consisting of SEQ ID NO:46, SEQ ID NO:52, SEQ ID NO:58 and SEQ ID NO:64 under said amplification conditions, wherein said second amplification oligonucleotide does not comprise a base region in addition to said target binding region that is capable of stably binding to a target nucleic acid containing said target sequence under said amplification conditions, and wherein said second amplification oligonucleotide optionally includes a 5' sequence that is recognized by an RNA polymerase or that enhances initiation or elongation by an RNA polymerase.

117. (Currently Amended) The method of claim 50, wherein the base sequence of said target binding region is fully complementary to the base sequence of said target sequence.

118. (Currently Amended) The method of claim 117 further comprising providing to said test sample a first amplification oligonucleotide comprising a target binding region under amplification conditions, wherein the base sequence of said target binding region is fully complementary to the base sequence of a target sequence selected from the group consisting of SEQ ID NO:48, SEQ ID NO:54, SEQ ID NO:60 and SEQ ID NO:66,

wherein said target binding region hybridizes to said target sequence under said amplification conditions,

wherein said first amplification oligonucleotide does not comprise a base region in addition to said target binding region that is capable of stably binding to a target nucleic acid containing said target sequence under said amplification conditions, and

wherein said first amplification oligonucleotide optionally includes a 5' sequence that is recognized by an RNA polymerase or that enhances initiation or elongation by an RNA polymerase.

119. (Currently Amended) The method of claim 118 further comprising providing to said test sample a second amplification oligonucleotide comprising a target binding region under said amplification conditions, wherein the base sequence of said target binding region is fully complementary to the base sequence of a target sequence selected from the group consisting of SEQ ID NO:45, SEQ ID NO:51, SEQ ID NO:57 and SEQ ID NO:63,

wherein said target binding region hybridizes to said target sequence under said amplification conditions,

wherein said second amplification oligonucleotide does not comprise a base region in addition to said target binding region that is capable of stably binding to a target nucleic acid containing said target sequence under said amplification conditions, and

wherein said second amplification oligonucleotide optionally includes a 5' sequence that is recognized by an RNA polymerase or that enhances initiation or elongation by an RNA polymerase.

120. (Currently Amended) The method of claim 118 further comprising providing to said test sample a second amplification oligonucleotide comprising a target binding region under said amplification conditions, wherein the base sequence of said target binding region is fully complementary to the base sequence of a target sequence selected from the group consisting of SEQ ID NO:46, SEQ ID NO:52, SEQ ID NO:58 and SEQ ID NO:64,

wherein said target binding region hybridizes to said target sequence under said amplification conditions,

wherein said second amplification oligonucleotide does not comprise a base region in addition to said target binding region that is capable of stably binding to a target nucleic acid containing said target sequence under said amplification conditions, and

wherein said second amplification oligonucleotide optionally includes a 5' sequence that is recognized by an RNA polymerase or that enhances initiation or elongation by an RNA polymerase.

121. (Currently Amended) The method of claim 51 further comprising providing to said test sample a first amplification oligonucleotide comprising a target binding region under amplification conditions, wherein the base sequence of said target binding region is at least 80% complementary to the base sequence of a target sequence selected from the group consisting of SEQ ID NO:48, SEQ ID NO:54, SEQ ID NO:60 and SEQ ID NO:66,

wherein said target binding region hybridizes to said target sequence under said amplification conditions,

wherein said first amplification oligonucleotide does not comprise a base region in addition to said target binding region that is capable of stably binding to a target nucleic acid containing said target sequence under said amplification conditions, and

wherein said first amplification oligonucleotide optionally includes a 5' sequence that is recognized by an RNA polymerase or that enhances initiation or elongation by an RNA polymerase.

122. (Currently Amended) The method of claim 121 further comprising providing to said test sample a second amplification oligonucleotide comprising a target binding region under amplification conditions, wherein the base sequence of said target binding regon is at least 80% complementary to the base sequence of a target sequence selected from the group consisting of SEQ ID NO:45, SEQ ID NO:51, SEQ ID NO:57 and SEQ ID NO:63,

wherein said target binding region hybridizes to said target sequence under said amplification conditions,

wherein said second amplification oligonucleotide does not comprise a base region in addition to said target binding region that is capable of stably binding to a target nucleic acid containing said target sequence under said amplification conditions, and

wherein said second amplification oligonucleotide optionally includes a 5' sequence that is recognized by an RNA polymerase or that enhances initiation or elongation by an RNA polymerase.

123. (Currently Amended) The method of claim 121 further comprising providing to said test sample a second amplification oligonucleotide comprising a target binding region under amplification conditioins, wherein the base sequence of said target binding region is at least 80% complementary to the base sequence of a target sequence selected from the group consisting of SEQ ID NO:46, SEQ ID NO:52, SEQ ID NO:58 and SEQ ID NO:64,

wherein said target binding region hybridizes to said target sequence under said amplification conditions,

wherein said second amplification oligonucleotide does not comprise a base region in addition to said target binding region that is capable of stably binding to a target nucleic acid containing said target sequence under said amplification conditions, and

wherein said second amplification oligonucleotide optionally includes a 5' sequence that is recognized by an RNA polymerase or that enhances initiation or elongation by an RNA polymerase.

124. (Currently Amended) The method of claim 52 further comprising providing to said test sample a first amplification oligonucleotide comprising a target binding region under amplification conditions, wherein the base sequence of said target binding region is fully complementary to the base sequence of a target sequence selected from the group consisting of SEQ ID NO:48, SEQ ID NO:54, SEQ ID NO:60 and SEQ ID NO:66,

wherein said target binding region hybridizes to said target sequence under said amplification conditions,

wherein said first amplification oligonucleotide does not comprise a base region in addition to said target binding region that is capable of stably binding to a target nucleic acid containing said target sequence under said amplification conditions, and

wherein said first amplification oligonucleotide optionally includes a 5' sequence that is recognized by an RNA polymerase or that enhances initiation or elongation by an RNA polymerase.

125. (Currently Amended) The method of claim 124 further comprising providing to said test sample a second amplification oligonucleotide comprising a target binding region under amplification conditions, wherein the base sequence of said target binding region is fully complementary to the base sequence of a target sequence selected from the group consisting of SEQ ID NO:45, SEQ ID NO:51, SEQ ID NO:57 and SEQ ID NO:63,

wherein said target binding region hybridizes to said target sequence under said amplification conditions,

wherein said second amplification oligonucleotide does not comprise a base region in addition to said target binding region that is capable of stably binding to a target nucleic acid containing said target sequence under said amplification conditions, and

wherein said second amplification oligonucleotide optionally includes a 5' sequence that is recognized by an RNA polymerase or that enhances initiation or elongation by an RNA polymerase.

126. (Currently Amended) The method of claim 124 further comprising providing to said test sample a second amplification oligonucleotide comprising a target binding region under amplification conditions, wherein the base sequence of said target binding region is fully complementary to the base sequence of a target sequence selected from the group consisting of SEQ ID NO:46, SEQ ID NO:52, SEQ ID NO:58 and SEQ ID NO:64,

wherein said target binding region hybridizes to said target sequence under said amplification conditions,

wherein said second amplification oligonucleotide does not comprise a base region in addition to said target binding region that is capable of stably binding to a target nucleic acid containing said target sequence under said amplification conditions, and

wherein said second amplification oligonucleotide optionally includes a 5' sequence that is recognized by an RNA polymerase or that enhances initiation or elongation by an RNA polymerase.

127. (Withdrawn) The kit of claim 53, wherein the base sequence of said first oligonucleotide comprises the base sequence of SEQ ID NO:5, SEQ ID NO:9, SEQ ID NO:13 or SEQ ID NO:17.

128. (Withdrawn) The kit of claim 53, wherein the base sequence of said first oligonucleotide consists of or is contained within the base sequence of SEQ ID NO:5, SEQ ID NO:9, SEQ ID NO:13 or SEQ ID NO:17.

129. (Withdrawn) The kit of claim 53, wherein the base sequence of said first oligonucleotide consists of the base sequence of SEQ ID NO:5, SEQ ID NO:9, SEQ ID NO:13 or SEQ ID NO:17.

130. (Withdrawn) The kit of claim 53, wherein the base sequence of said first oligonucleotide comprises the base sequence of SEQ ID NO:7, SEQ ID NO:11, SEQ ID NO:15 or SEQ ID NO:19.

131. (Withdrawn) The kit of claim 53, wherein the base sequence of said first oligonucleotide consists of or is contained within the base sequence of SEQ ID NO:7, SEQ ID NO:11, SEQ ID NO:15 or SEQ ID NO:19.

132. (Withdrawn) The kit of claim 53, wherein the base sequence of said first oligonucleotide consists of the base sequence of SEQ ID NO:7, SEQ ID NO:11, SEQ ID NO:15 or SEQ ID NO:19.

133. (Currently Amended) The kit of claim 53, wherein the base sequence of said target binding region of each said oligonucleotide is at least 80% complementary to the base sequence of said target sequence of said oligonucleotide.

134. (Currently Amended) The kit of claim 53, wherein the base sequence of said target binding region of each said oligonucleotide is fully complementary to the base sequence of said target sequence of said oligonucleotide.

135. (Currently Amended) The kit of claim 53, wherein the base sequence of each said oligonucleotide is at least 80% complementary to the base sequence of said target sequence of said oligonucleotide.

136. (Currently Amended) The kit of claim 53, wherein the base sequence of each said oligonucleotide is fully complementary to the base sequence of said target sequence of said oligonucleotide.

137. (Currently Amended) The kit of claim 59, wherein the base sequence of said target binding region of each said oligonucleotide is at least 80% complementary to the base sequence of said target sequence of said oligonucleotide.

138. (Currently Amended) The kit of claim 59, wherein the base sequence of said target binding region of each said oligonucleotide is fully complementary to the base sequence of said target sequence of said oligonucleotide.

139. (Currently Amended) The kit of claim 59, wherein the base sequence of each said oligonucleotide is at least 80% complementary to the base sequence of said target sequence of said oligonucleotide.

140. (Currently Amended) The kit of claim 59, wherein the base sequence of each said oligonucleotide is fully complementary to the base sequence of said target sequence of said oligonucleotide.

141. (Currently Amended) The kit of claim 60, wherein the base sequence of said target binding region of each said oligonucleotide is at least 80% complementary to the base sequence of said target sequence of said oligonucleotide.

142. (Currently Amended) The kit of claim 60, wherein the base sequence of said target binding region of each said oligonucleotide is fully complementary to the base sequence of said target sequence of said oligonucleotide.

143. (Currently Amended) The kit of claim 60, wherein the base sequence of each said oligonucleotide is at least 80% complementary to the base sequence of said target sequence of said oligonucleotide.

144. (Currently Amended) The kit of claim 60, wherein the base sequence of each said oligonucleotide is fully complementary to the base sequence of said target sequence of said oligonucleotide.

145. (Withdrawn) The kit of claim 84, wherein the base sequence of said first oligonucleotide comprises the base sequence of SEQ ID NO:5, SEQ ID NO:9, SEQ ID NO:13 or SEQ ID NO:17.

146. (Withdrawn) The kit of claim 84, wherein the base sequence of said first oligonucleotide consists of or is contained within the base sequence of SEQ ID NO:5, SEQ ID NO:9, SEQ ID NO:13 or SEQ ID NO:17.

147. (Withdrawn) The kit of claim 84, wherein the base sequence of said first oligonucleotide consists of the base sequence of SEQ ID NO:5, SEQ ID NO:9, SEQ ID NO:13 or SEQ ID NO:17.

148. (Withdrawn) The kit of claim 84, wherein the base sequence of said first oligonucleotide comprises the base sequence of SEQ ID NO:7, SEQ ID NO:11, SEQ ID NO:15 or SEQ ID NO:19.

149. (Withdrawn) The kit of claim 84, wherein the base sequence of said first oligonucleotide consists of or is contained within the base sequence of SEQ ID NO:7, SEQ ID NO:11, SEQ ID NO:15 or SEQ ID NO:19.

150. (Withdrawn) The kit of claim 84, wherein the base sequence of said first oligonucleotide consists of the base sequence of SEQ ID NO:7, SEQ ID NO:11, SEQ ID NO:15 or SEQ ID NO:19.

151. (Currently Amended) The kit of claim 84, wherein the base sequence of said target binding region of each said oligonucleotide is at least 80% complementary to the base sequence of said target sequence of said oligonucleotide.

152. (Currently Amended) The kit of claim 84, wherein the base sequence of said target binding region of each said oligonucleotide is fully complementary to the base sequence of said target sequence of said oligonucleotide.

153. (Currently Amended) The kit of claim 84, wherein the base sequence of each said oligonucleotide is at least 80% complementary to the base sequence of said target sequence of said oligonucleotide.

154. (Currently Amended) The kit of claim 84, wherein the base sequence of each said oligonucleotide is fully complementary to the base sequence of said target sequence of said oligonucleotide.

155. (Currently Amended) The kit of claim 84 further comprising a third oligonucleotide from 18 to 35 bases in length that hybridizes to a target sequence present in target nucleic acid derived from a *Cryptosporidium parvum* organism under stringent conditions, said target sequence being selected from the group consisting of SEQ ID NO:32, SEQ ID NO:36, SEQ ID NO:40 and SEQ ID NO:44.

156. (Currently Amended) The kit of claim 155, wherein each said oligonucleotide has a base region that is at least 80% complementary to the base sequence of said target sequence of said oligonucleotide.

157. (Currently Amended) The kit of claim 155, wherein each said oligonucleotide has a base region that is fully complementary to the base sequence of said target sequence of said oligonucleotide.

158. (Currently Amended) The kit of claim 155, wherein the base sequence of each said oligonucleotide is at least 80% complementary to the base sequence of said target sequence of said oligonucleotide.

159. (Currently Amended) The kit of claim 155, wherein the base sequence of each said oligonucleotide is fully complementary to the base sequence of said target sequence of said oligonucleotide.